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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KASSA, TIGABU	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
11/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,440	KUHAR ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-14 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-14, and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other _____

DETAILED ACTION

This Office Action is in response to the amendment filed July 30, 2009. **Claims 1-5, 7-14, and 16 are pending.** **Claims 1-5, 7-14, and 16 are under examination in the instant office action**. Claims 6 and 15 are cancelled. Applicant's amendment has necessitated a new ground of rejection. Accordingly, this Action is made FINAL.

Moot Rejections/Objections

The rejection of claims 6 and 15 cited in the previous office action mailed on February 04, 2009 are moot, because said claim(s) has/have been cancelled.

Withdrawn rejections

Applicant's amendments and arguments filed on 07/30/09 are acknowledged and have been fully considered. All rejections applied in the previous office action are hereby withdrawn as a result of applicants claim amendments.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5, and 11-16 are rejected under 35 U.S.C. § 102(e) as being anticipated by Platteeuw (US Patent No. 7018658) .

Instant claim1 recites a controlled release pharmaceutical formulation comprising a pellet core having a diameter from about 0.5 to about 2.00 mm from which a low dose active substance can be released wherein the said pellet core is coated with a gasteroresistant and/or release controlling coating. Instant claim 3 recites a formulation according to claim 1 wherein the polymer is an acrylic alkylcellulose, hydroxyalkylcellulose or combinations thereof. Instant claim 5 recites the formulation of claim 1 where in the diameter of the core is about 0.5-1.25 mm.

Platteeuw discloses a controlled release formulation of tamsulosin in a pellet core (abstract). Platteeuw discloses a pharmaceutical pellet composition comprising tamsulosin as an active ingredient and having an advantageous coating layer with respect to obtaining an extended release profile (column 2, lines 19-22). Each pellet comprises **a pellet core, which has a diameter within the range of 0.3-0.9 mm**, comprising **tamsulosin hydrochloride, microcrystalline cellulose, a pharmaceutically acceptable water permeable acrylic polymer, and water** (column 2, lines 24-28). Each pellet core is surrounded by an **outer layer coat, which comprises a pharmaceutically acceptable acid-resistant acrylic polymer, in an amount, calculated on a dry pellet core basis, that is within the range of 2.5-15%** (column 2, lines 28-32).

Instant claim 11 recites the formulation of claim 1 wherein the pellets are formed into capsules, sachets, or tablets. Instant claim 12 recites the formulation of claim 1 wherein the cores are prepared by extrusion or spheronization. Instant claim 13 recites the formulation claim 1 wherein the substance is tamsulosin or salt thereof. Instant claim 14 recites a process for preparing the formulation of claim 1 comprising blending ingredients, granulation, extrusion,

spheronization drying and optionally coating. Instant claim 16 recites a method of for treating benign prostatic hyperplasia comprising administering the formulation of claim 13.

Platteeuw also discloses process of preparing the controlled release formulation of tamsulosin comprising granulating a mixture of tamsulosin hydrochloride, microcrystalline cellulose, acrylic polymer, water and optionally auxiliary ingredients to form wet pellet cores, drying the wet pellet cores to a residual amount of water of 2-10%, sieving the dried pellet cores to obtain a fraction within the size range of 0.3-0.9 mm, coating the sieved dried pellet cores with a coating composition that comprises an acid-resistant water soluble acrylic polymer, and drying the coated pellets, wherein the coating step is sufficient to provide the dried coated pellets with 2.5-15 mass % of the coating composition, calculated on the dry pellet core basis (column 2, lines 41-52 and column 5, lines 34-53). Platteeuw also discloses that the resulting granulate may be used for making final dosage forms, **capsules as well as tablets** (column 1, lines 55-57). Platteeuw also discloses that tamsulosin is useful for treatment of cardiac insufficiencies and benign prostatic hyperplasia(column 1, lines 20-22). Platteeuw also discloses **a method for treating the symptoms of benign prostatic hyperplasia, which comprises administering an effective amount of the pellets** according to the above description to a patient in need thereof (see claim 20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically taught or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 1 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platteeuw (US Patent No. 7018658).

Applicant Claims

The claimed subject matter of instant claims 1 are set forth above. Instant claim 7 recites the pharmaceutical formulation of claim 1 wherein the mass of the applied coating from about 5 to about 10% relative to the mass of the dried pellet. Instant claim 8 recites the pharmaceutical

formulation of claim 7 wherein the mass of the applied coating from about 5 to about 10% relative to the mass of the dried pellet.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Platteeuw are set forth above. Additionally, Platteeuw teaches the coating step is sufficient to provide the dried coated pellets with **2.5-15 mass %** of the coating composition, calculated on the dry pellet core basis (column 2, lines 50-53).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

The mass of the applied coating range**2.5-15 mass %** taught by Platteeuw is not an anticipation range rather it is a range that renders the limitations of instant claims 7-8 obvious.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention to apply the coating layer having the mass ranges as recited in instant claims 7-8 because Platteeuw teach Platteeuw teaches the coating step is sufficient to provide the dried coated pellets with **2.5-15 mass %** of the coating composition, calculated on the dry pellet core basis (column 2, lines 50-53). A *prima facie* case of obviousness exists in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). An ordinary skilled artisan would have had a reasonable expectation of success upon following the teachings of Platteeuw, because Platteeuw teaches controlled release formulations a drug in a pellet core coated with a layer.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claims 2, 4, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platteeuw (US Patent No. 7018658) as applied to claims 1, 3, 5, and 11-16 above, and further in view of Chen et al. (US Patent 6602522).

Applicant Claims

The claimed subject matter of instant claims 1 and 3 are set forth above. Instant claim 2 recites a controlled release pharmaceutical formulation comprising a pellet core a diameter from about 0.5 to about 2.00 mm, at least one insoluble permeable polymer, a surfactant, and optionally other excipients. Instant claim 4 recites the formulation according to claim 3 wherein the polymer is an ethylacrylate/methylmethacrylate copolymer in a ratio of 2:1 which is optionally a 30% aqueous dispersion. Instant claim 9 recites the formulation according to claim 1 wherein the coating comprises a polymer soluble above 5.5 and a polymer soluble independent of pH. Instant claim 10 recites the formulation according to claim 9 wherein the polymers are an anionic copolymer of methacrylic acid and ethylacrylate and an ethylacrylate and methylmethacrylate copolymer, respectively.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Platteeuw are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Platteeuw does not explicitly teach the inclusion the specific copolymers recited in claims 4 and 9-10. Platteeuw does not explicitly teach the inclusion of a surfactant in the formulation as recited in claim 2. These deficiencies are cured by the teachings of Chen et al..

Chen et al. teach a pharmaceutical composition comprising a core and a coating layer (abstract). The core contains a therapeutic active ingredient, **a surface active agent**, filler, an alkaline agent, and a binder (column 2, lines 10-20). The binder can be a water-insoluble polymer such as a **polymethacrylic acid copolymer such as Eudragit NE30D (ethlacrylate/jmethylmehacrylate 2:1) which is available as a 30% aqueous dispersion** (column 3, line 19-26). The enteric coating resists acid up to **about pH 5 or higher** (column 3, lines48-50). The examiner notes that the pH 5 disclosed by Chen et al. is about pH 5.5 in instant claim 9. Moreover, Chen et al. teach the same polymers as specified in instant claims 9 and 10 and the pH solubility of the polymer is an inherent property of the polymers. The coating, therefore, controls the release of the active agent. The coating preferably comprises a combination of polymers including, for example **Eudragit L30-55 (methacrylc acid and ethylacrylate) and Eudragit NE30D (ethlacrylate/methylmehacrylate 2:1)**. The active ingredient and other ingredients for the core are combined, granulated, dried, formed into tablets, and coated (column 4, lines 20-33).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Platteeuw via the incorporation of

the copolymers recited in claims 4 and 9-10 in the formulation because Chen et al. teach a controlled release formulation of comprising the polymers and a surfactant. An ordinary skilled artisan would have been motivated to use the specific polymer recited in claims 4 and 9-10 because Platteeuw teach that such polymers are useful for gastroresistant coating since such polymers are not soluble in acidic aqueous medium, while they are soluble in neutral or basic aqueous medium (column 4, lines 59-60). An ordinary skilled artisan would have been motivated to use surfactant in the formulation because surfactant will help the spreading and wetting potential of the formulation and also for improving stability of the formulation. An ordinary skilled artisan would have had a reasonable expectation of success upon combination of Platteeuw and Chen et al., because both references teach controlled release formulations of comprising a pellet core containing an active coated with a controlled release layer.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary

Conclusion

Claims 1-5, 7-14, and 16 are rejected. Claims 6 and 15 are cancelled. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 11/05/09

/YVONNE L. EYLER/

Supervisory Patent Examiner, Art Unit 1619